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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/417,534 10/14/99 BUCHA

E 209282.0006

000570 HM12/0202  
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA PA 19103

EXAMINER

GAREL, G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

13

DATE MAILED:

02/02/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

|                              |                              |                  |  |
|------------------------------|------------------------------|------------------|--|
| <b>Office Action Summary</b> | Application No.              | Applicant(s)     |  |
|                              | 09/417,534                   | BUCHA ET AL.     |  |
|                              | Examiner<br>Gailene R. Gabel | Art Unit<br>1641 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) Responsive to communication(s) filed on 09 December 2000.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 and 32 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16 and 32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
    1. received.
    2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
    3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

|  |  |
|--|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 15) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)             | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>48</u> | 19) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election of Group I, claims 1-16 and 32, with traverse, in Paper No. 12, filed 12/9/00, is acknowledged and has been entered. Claims 17-31 and 33 have been cancelled without prejudice. The preliminary amendment filed 10/14/99 in Paper No. 7 is also acknowledged and has been entered. Claim 1 has been amended. Accordingly, claims 1-16 and 32 are pending and under examination.

### *Priority*

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

### *Drawings*

3. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings in this application are also objected to by the Draftsperson (see PTO-948 attached). Correction is required. However, formal correction of noted defect can be deferred until application is allowed by the examiner.

### *Information Disclosure Statement*

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4. The Information Disclosure Statement (PTO-1449) filed 3/3/00 in Paper No. 4 is acknowledged. Document nos. 2 332 287 (France), DE 27 12 344 A1 (Germany), EP 0 591 807 A2 (Europe), and EP 0 700 933 A1 (Europe) were not considered because neither an English translation nor a statement of relevancy was provided therefor. The Information Disclosure Statement (PTO-1449) filed 3/13/00 in Paper No. 8 is acknowledged. Document number DE 689 10587 T2 (Germany) was not considered because neither an English translation nor a statement of relevancy was provided therefor.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-16 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step a) is vague and indefinite in reciting "surface of a plastic material from monomers containing" because it is unclear as to whether the surface is "made from", "obtained from", or derived from" monomers.

Claims 2-13 and 32 have improper antecedent basis problem in reciting "Interactive system according to claim...". Change to --The interactive system according to claim ...-- for proper antecedent basis.

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Claim 3 recites improper Markush language in reciting "the plastic material is a plastic material from". Change to --the plastic material is a material selected from the group consisting of... and --for proper Markush language.

Regarding claim 3, the phrase "with other polymerizable substances" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "other polymerizable substances"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 4 recites improper Markush language in reciting "the linker is selected from". Change to -- the linker is selected from the group consisting of --for proper Markush language.

Claim 5 is vague and indefinite in reciting "spun material" because it is unclear what element is encompassed by the limitation.

Claim 6 is indefinite in reciting "the system is present in the form of a capillary tube system ..." because it is unclear what Applicants intend to encompass in reciting "present in the form of".

Regarding claim 7, "and/or" renders the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention.

Claim 8 is indefinite in reciting "Ni-NTA". Abbreviations or acronyms should be fully defined at least one time in a given set of claims.

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Claim 9 recites improper Markush language and overlapping Markush groups in reciting "the protein is selected from". Change to --the protein is selected from the group consisting of ... and-- for proper Markush language.

In claim 10, change "chemilumenescent" to --chemiluminescent-- for correct spelling.

Claim 12 recites improper Markush language in reciting "an anticoagulant selected from". Change to --an anticoagulant selected from the group consisting of ... and-- for proper Markush language.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claims 15-16 have improper antecedent basis problem in reciting "Composition according to claim...". Change to --The composition according to claim ...-- for proper antecedent basis.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Alternatively, claim 15 is indefinite in reciting "in the form of ..." because it is unclear what Applicants intend to encompass in reciting "in the form of".

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim

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is an omnibus type claim. Alternatively, claim 16 is indefinite in reciting "in the form of ..." because it is unclear what Applicants intend to encompass in reciting "in the form of".

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Claim 32, as recited, merely claims the "interactive system for use in preparing an agent ...".

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by DANIEL (US 4,086,199).

Daniel discloses an interactive system which are latex polymer particles which function as biological carriers for protein substances. The particles have a core which comprises alkyl acrylates and methacrylates and a cross-linker comprising polyethylene glycol dimethacrylate which gives the polymer particles greater resistance to solvents (see columns 1-2). According to Daniel, the latex particles are very stable, chemically and mechanically, at extended periods of time, remain stable at varying pH levels and temperature (copolymerization temp ranges from 5 to 90 °C). The biologically active

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substances such as proteins are coupled or adsorbed into the carrier particles (see column 4).

7. Claims 1-8, 11, 13-14, 16, and 32 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by DeCROSTA et al. (US 4,086,199).

Decrosta et al. disclose a drug delivery system in the form of hydrogel beads including interpenetrating polymer network which have superior drug loading and release capacity (see Abstract). Specifically, DeCrosta et al. disclose a first polymer substrate comprising acrylic swelling agent, methyl methacrylate or acrylic acid, and a crosslinking agent, ethylene glycol dimethacrylate (see column 3, lines 21-36 and column 5, lines 10-17). The hydrogel beads are loaded with pharmaceutical active compositions wherein the loading is accomplished by swelling the hydrogel. The pharmacologically active drugs include those enumerated in column 6, lines 32-62.

8. Claims 1-11, 13-14, 16, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by CHA et al. (US 5,665,428).

Cha et al. disclose peptide/protein biodegradable drug delivery systems prepared as microspheres or hydrogels which are useful and stable at high temperatures, i.e. 50 °C (see Abstract and column 6, lines 54-58). Cha et al. teach the microsphere as ABA block copolymers comprising a hydrophilic B block segment which is preferably polyethylene glycol, and a biodegradable hydrophobic A block segment which can be

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polyethylene carbonate. According to Cha et al., the release profile of the pharmaceutically active drugs from the polymers may be adjusted by the addition of carboxyl functional group into the hydrophobic block; thereby, further extending a sustained release of the drug (see column 9, lines 19-28). Column 9, lines 41-53 lists pharmaceutically active polypeptides for use in the drug delivery system such as growth hormones, secretin, and gastrin, etc.

9. Claims 1-16 and 32 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by HUBBELL et al. (US 5,410,016).

Hubbell et al. disclose photopolymerizable, biodegradable hydrogels as tissue contacting materials or controlled release carriers. Specifically, the polymerizable region comprises dimethacrylates and oligomethacrylates (see column 9, lines 7-18). The polymerizable, macromer includes a core, an extension on each end, and an end cap wherein the core includes hydrophilic polyethylene glycol. The physiologically and pharmacologically active drugs for controlled delivery include proteins, hormones, enzymes, antibiotics, and carbohydrates which include hyaluronic acid, heparin, and heparan sulfate.

10. For reasons aforementioned, no claims are allowed

***Remarks***

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11. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Rhee et al. disclose injectable and implantable biomaterials for filling or blocking lumens and voids of the body.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Gail Gabel  
Patent Examiner  
Group 1641

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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6/29/01